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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/933,938	08/21/2001	Pathiraja A. Gunatillake	1207.008US1	7489

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EXAMINER

SERGEANT, RABON A

ART UNIT	PAPER NUMBER
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1711

DATE MAILED: 11/20/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/933,938

Applicant(s)
Gunatillake et al.

Examiner
Rabon Sergeant

Art Unit
1711



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep 4, 2002
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 63-108, 111, 112, and 117-128 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 63-108, 111, 112, and 117-128 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

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1. Under the provisions of 37 CFR 1.126, claims 122-125 set forth within the amendment of September 4, 2002 have been renumbered as claims 125-128. Claims 122-124 were added by the amendment of April 8, 2002 and are pending. All further communications must refer to the new claims as claims 125-128.

2. The amendment filed September 4, 2002 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Applicants' 'incorporation by reference' constitutes "new matter". Applications must be complete as filed.

Applicant is required to cancel the new matter in the reply to this Office Action.

3. Claim 119 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicants have failed to provide any guidance with respect to the production of an artificial organ.

4. Claims 122-124 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not clear how the terminology denoted by relative term, "resistant", patentably limits or distinguishes the claims. It is not clear that the language constitutes definitive limitations.

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5. Claims 125-128 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. With respect to claim 125, support has not been found for the use of the language, "greater than about 295 million cycles". The cited example provides support for only two specific values, and the values are pertinent only for valves of two specific thicknesses. With respect to claims 126-128, support has not been found for the use of the term, "about". The examples provide support for only the recited values. Furthermore, it is unclear what constitutes a "degradation resistance ranking". It is unclear what the ranking refers to or what the basis for the ranking is.

6. Claims 126-128 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear how to interpret the "degradation resistance ranking" with respect to being a definitive limitation. It is unclear what basis exists for the ranking to have any definitive meaning.

7. Claims 81-103 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Adequate support has not been provided for claiming that the molecular weights are number average molecular weights. See paragraph 2 of this Office action.

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8. Claims 63-103 and 117-128 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Despite applicants' response, the macrodiamine of claim 63 is not mutually exclusive from the formula (I) compound. Furthermore, it is unclear how the formula (I) soft segment component is to differ structurally from the chain extender of formula (I); in other words, it is not clear that the claim language allows for the respective compounds, based on formula (I), being different.

9. Claim 95 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The language, "the macrodiamine compound of formula (I)", lacks antecedent basis.

10. Claims 63-108, 111, 112, and 117-128 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear how R_5 and R_6 can ever be hydrogen; however, the definition provides for the variables being hydrogen.

Furthermore, with respect to claims 104-108 and 112, it is unclear how the polyurethane-urea is produced when only hydroxyl functional reactants are utilized. The claims do not require the use of an amine functional compound.

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11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 63-108, 111, 112, and 117-128 are rejected under 35 U.S.C. 103(a) as being unpatentable over Szycher et al. ('627) or WO 98/13405 or JP 4-248826, each in view of Li et al. ('724) and Ohtaki et al. ('085).

The primary references disclose the production of polysiloxane-polyurethane (urea) polymers having enhanced biocompatibility wherein active hydrogen group containing polysiloxanes are combined with additional active hydrogen compounds, such as polyethers or polycarbonates, and the resulting mixtures are reacted with polyisocyanates to yield polymers having enhanced characteristics.

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13. While Szycher et al. and JP 4-248826 disclose that amine functional polysiloxanes may be used, the references further disclose the use of hydroxyl functional polysiloxanes. Additionally, none of the primary references disclose the specific use of an amine functional siloxane as a chain extender. However, Li et al. specifically teach the use of amine functional polysiloxane compounds, which overlap applicants' claimed soft segment and hard segment compounds, in the production of biocompatible polyureas and polyurethane ureas having improved physical and mechanical properties. Furthermore, Ohtaki et al. disclose the amino functional tetraorganodisiloxanes as reactants within polyurethanes.

14. Therefore, since applicants' claimed amine functional polysiloxanes were known reaction constituents for polyurethaneurea and since they were known to bestow improved properties, including improved biocompatibility, to urethanes, it would have been *prima facie* obvious to utilize them as reactants within the compositions of the primary references, so as to arrive at the instant invention.

15. Applicants' arguments have been considered; however, the arguments fail to appreciate the significance of the teachings of the secondary references and fail to consider the scope of the instant claims' limitations. Firstly, the position is taken that applicants' claims do not differentiate the soft segment compound of formula (I) with the hard segment compound of formula (I); therefore, the references need merely teach the desirability of incorporating an amine functional polysiloxane which meets the claimed formula (I) into a polyurethaneurea. The secondary references clearly provide this teaching. Furthermore, it would have been obvious to utilize the

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amine functional siloxane within either or both of the reaction components of the instant composition, because one would have reasonably expected the amine functional polysiloxane to convey beneficial properties to the composition, regardless of its means of introduction. Additionally, despite applicants' argument, the compound of Li et al. clearly meets the instantly claimed amine functional polysiloxane; applicants' argued linkage within Li et al. is well within the scope of the claimed divalent linker. Lastly, despite applicants' arguments, claims 104 and 112 do not even require that the argued amine functional polysiloxane be used; it is simply a member of a Markush group; therefore, it is unclear what critical distinctions can be attributed to the argued amine functional polysiloxane.

Any inquiry concerning this communication should be directed to R. Sergent at telephone number (703) 308-2982.


RABON SERGENT
PRIMARY EXAMINER

R. Sergent

November 17, 2002